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07/992,089 12/17/92 CARLING

C 1103326-018

EXAMINER

HENLEY III, R

12M2/1001

WHITE & CASE
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

ART UNIT

PAPER NUMBER

1205

DATE MAILED:

10/01/93

10/01/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3/19/93 and 7/22/93 ☒ This action is made final.
A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-3 AND 5-13 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-3 AND 5-13 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

CLAIMS 1-3 AND 5-13 ARE PRESENTED FOR EXAMINATION

The Information Disclosure Statement filed March 19, 1993 and applicants' amendment filed July 22, 1993 have been received and entered into the application. Accordingly, claims 1-3 and 5-7 have been amended; claim 4 has been cancelled; and claims 8-13 have been added. In view thereof, the rejection of claim 4 under 35 USC 101 and of claims 1-3 and 5-7 under 35 USC 112, second paragraph as set forth at pages 2 and 3 of the last Office action dated February 19, 1993 are withdrawn. Also, as reflected by the attached, completed form PTO-1449, the submitted references have been considered.

Claims 1-3 and 5-13 are rejected under 35 U.S.C. § 103 as being unpatentable over Brattsand et al. and Murakami et al. in view of applicants' acknowledgements at page 3 of the present specification for the reasons of record as applied to claims 1-3 and 5-7 in the last Office action at pages 4-6.

Applicants' arguments have been carefully considered by the Examiner, but fail to persuade the Examiner of error in his determination of obviousness.

As is evident by the instant rejection being based on 35 USC 103 rather than 35 USC 102, the Examiner agrees with applicants' observation that Brattsand does not disclose or claim the use of corticoid compounds in compositions with other active ingredients such as β_2 -adrenoreceptor agonists as is instantly claimed. However, it is

maintained that it would have nevertheless been obvious to do what applicants are doing in view of the teachings of the secondary references.

With respect to the teachings of Murakami et al. and contrary to applicants' opinion, it is not seen that the patentees fail to teach applicants' active ingredient since formoterol is clearly identified by its chemical designation at example 22. Also, applicants are apparently of the position that the teaching of the patentees that the compounds may be in the form of aerosols as inhalations should be discarded since at example 22 an injectable form is demonstrated. The Examiner, however, cannot follow applicants' reasoning because examples do not serve to limit the broader teachings of the patentees and, as is well settled in the law, one cannot ignore the broader, instructive disclosure of a reference which teaches how to modify exemplary compositions, In re Courtright, 377 F.2d 647, 153 USPQ 735 (CCPA 1967).

Applicants also argue that none of the European patent applications discussed at page 3 of the present specification teach applicants' specific combination. However, the references nevertheless clearly support the instant conclusion of obviousness as they establish that the concept of using steroids and β_2 -adrenoreceptor agonists in combination by inhalation for treating respiratory disorders was known to the artisan.

Finally, applicants assert that the instant combination of active ingredients exhibits significantly enhanced and unexpected properties over the prior art combinations by way of synergism. However, it has not been demonstrated on the

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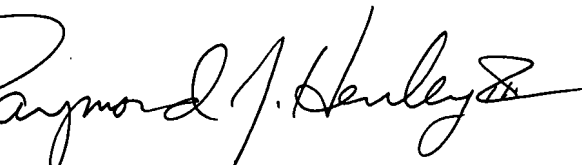
record, by means of appropriate experimental data, that applicants' combination produces any unobvious or unexpected results. The mere unsupported arguments of applicants are insufficient with such data.

Thus, for the above reasons, the claims are deemed to be properly rejected under 35 USC 103 and none are allowed.

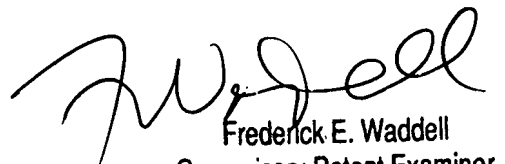
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND J. HENLEY III
PATENT EXAMINER
GROUP 120 - ART UNIT 125



Frederick E. Waddell
Supervisory Patent Examiner
Group 120

Henley; rjh
October 1, 1993